

## PATENT COOPERATION TREATY

## PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY  
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference <b>ENT 5</b>	<b>FOR FURTHER ACTION</b> See Form PCT/IPEA/416	
International application No. <b>PCT/SE2004/000818</b>	International filing date (day/month/year) <b>26.05.2004</b>	Priority date (day/month/year) <b>30.05.2003</b>
International Patent Classification (IPC) or national classification and IPC <b>A61F 2/18, H04R 25/02 // A61C 8/00</b>		
Applicant <b>Entific Medical Systems AB et al</b>		
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>3</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> (sent to the applicant and to the International Bureau) a total of <u>2</u> sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>		
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>		
Date of submission of the demand <b>06.12.2004</b>	Date of completion of this report <b>05.09.2005</b>	
Name and mailing address of the IPEA/SE Patent- och registreringsverket Box 5055 S-102 42 STOCKHOLM Facsimile No. +46 8 667 72 88	Authorized officer <b>Leif Brander/MP</b> Telephone No. +46 8 782 25 00	

Form PCT/IPEA/409 (cover sheet) (April 2005)

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/SE2004/000818

## Box No. I Basis of the report

## 1. With regard to the language, this report is based on:

- ☒ the international application in the language in which it was filed
- ☐ a translation of the international application into \_\_\_\_\_, which is the language of a translation furnished for the purposes of:
- ☐ international search (Rules 12.3(a) and 23.1(b))
- ☐ publication of the international application (Rule 12.4(a))
- ☐ international preliminary examination (Rules 55.2(a) and/or 55.3(a))

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

- ☐ the international application as originally filed/furnished
- ☒ the description:
- pages 1 - 6 as originally filed/furnished
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- ☒ the claims:
- pages \_\_\_\_\_ as originally filed/furnished
- pages\* \_\_\_\_\_ as amended (together with any statement) under Article 19
- pages\* 1 - 2 received by this Authority on 12.08.2005
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- ☒ the drawings:
- pages 1 - 3 as originally filed/furnished
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/figs \_\_\_\_\_
- ☐ the sequence listing (specify): \_\_\_\_\_
- ☐ any table(s) related to the sequence listing (specify): \_\_\_\_\_

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/figs \_\_\_\_\_
- ☐ the sequence listing (specify): \_\_\_\_\_
- ☐ any table(s) related to the sequence listing (specify): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superseded."

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/SE2004/000818

**Box No. V** Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

## 1. Statement

Novelty (N)	Claims	<u>1-8</u>	YES
	Claims		NO
Inventive step (IS)	Claims	<u>1-8</u>	YES
	Claims		NO
Industrial applicability (IA)	Claims	<u>1-8</u>	YES
	Claims		NO

## 2. Citations and explanations (Rule 70.7)

New amended claims were filed on 12.08.2005.

The invention relates to an implant device for bone anchored hearing aids.

Relevant documents cited in the International Search Report:

- 1: EP 0715838 A2
- 2: US 4612915 A

The cited documents represent the general state of the art.

The invention defined in amended claims 1-8 is not disclosed by these documents.

The cited prior art does not give any indication that would lead a person skilled in the art to the claimed fixture and abutment sleeve made as a pre-mounted unit by means of a screw connection. Therefore, the claimed invention is not obvious to a person skilled in the art.

According to the arguments stated above, the invention claimed in claims 1-8 is novel, considered to involve an inventive step and have industrial applicability.

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## CLAIMS

5 1. An implant device for bone anchored hearing aids of the type which comprises a screw-shaped anchoring element (fixture) (1) for anchorage in the bone tissue, an abutment sleeve (2) for skin penetration and arranged to be connected to the fixture (1) by means of a separate screw connection (3) and a tool (4) for installing the implant into the bone tissue characterized in that the fixture (1) and the abutment sleeve (2) are made as a pre-mounted unit by means of the screw connection (3) which unit is arranged to be installed in one step by means of said tool (4) which is arranged to cooperate with a tool engaging portion (5) on the abutment sleeve (2).

20 2. An implant device according to claim 1 characterized in that the fixture (1) is a self-tapping fixture and provided with a flange (1b).

25 3. An implant device according to claim 1 characterized in that the tool engaging portion (5) on the abutment sleeve comprises a number of symmetrically arranged recesses or holes (8).

30 4. An implant device according to claim 3 characterized in that the tool (4) is provided with a lower, central protruding portion (15) with a number of peripherally located, in the longitudinal direction of the tool extending spikes (16) which spikes during tightening, insertion of the implant unit, are arranged to cooperate with said holes or recesses (8) on the abutment sleeve (2).

35 5. An implant device according to claim 1 characterized in that the tool (4) comprises a first connecting part (6) for installation of the pre-mounted

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implant device by means of a machine driver as well as a second connecting part (7) for manual insertion of the implant device.

- 5      6. An implant device according to claim 1 c h a r a c -  
t e r i z e d i n that the tool (4) comprises a resili-  
ent ring (9) for cooperation with the edge (10) of the  
abutment sleeve in order to provide a lifting function.
- 10     7. An implant device according to claim 6 c h a r a c -  
t e r i z e d i n that the pre-mounted implant device is  
delivered steril in a plastic package (11) comprising a  
titanium packaging sleeve (12) in order to retain the im-  
plant device in a predetermined position in the plastic  
15     package (11), and after the plastic package (11) has been  
broken before use the implant device is arranged to be se-  
parated from the titanium packaging sleeve (12) by means  
of said tool (4) and its lifting function.
- 20     8. An implant device according to claim 7 c h a r a c -  
t e r i z e d i n that a sealing ring (18) is arranged  
on the cylindrical outer surface of the plastic package  
(11) to provide a tightening between the plastic package  
and a screw lid (17), said sealing ring (18) being adjus-  
25     table in the longitudinal direction to provide a tighte-  
ning even for different positions of the lid (17) on the  
package.
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